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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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CIVIL MINUTES - GENERAL

Case No.	CV 09-7088 PSG (Ex)	Date	January 13, 2011
Title	Ivan Goldsmith v. Allergan, Inc.		

Present:	The Honorable Philip S. Gutierrez, United States District Judge

Wendy K. Hernandez	Not Present	n/a
Deputy Clerk	Court Reporter	Tape No.

Attorneys Present for Plaintiff(s):	Attorneys Present for Defendant(s):
Not Present	Not Present

Proceedings: (In Chambers) Order Granting Defendant's Motion to Dismiss

Pending before the Court is Defendant's Motion to Dismiss Plaintiff's fourth amended complaint. The Court heard oral argument on the matter on January 10, 2011. After considering the moving and opposing papers, as well as the oral arguments, the Court GRANTS Defendant's Motion.

I. Background

Plaintiff Ivan Goldsmith ("Plaintiff"), on behalf of himself and all others similarly situated, filed suit in this Court on September 29, 2009 against Defendant Allergan, Inc. ("Defendant").[1] Defendant manufactures Botox Cosmetic ("Botox"), a physician-administered pharmaceutical used to treat facial wrinkles. Defendant allegedly marketed Botox as a "multi-use" product to encourage administering physicians to use a single vile of Botox for more than one patient. According to Plaintiff, it was not until he built his practice and invested in the multi-use vials of Botox that he discovered that the product was suitable for single use not multi use, meaning that one vile should be used for one patient only.

Plaintiff filed a Fourth Amended Complaint ("Complaint"), asserting two claims based on his use of Defendant's Botox product in his medical practice: (1) violation of California's false advertising law ("FAL"), Cal. Bus. & Prof. Code § 17500; and (2) violation of California's unfair competition law ("UCL"), Cal. Bus. & Prof. Code § 17200. For the reasons that follow, the Court GRANTS Defendant's motion to dismiss.

[1] The facts in this Background section are not disputed and are taken from the Fourt Amended Complaint and the parties' motion papers.

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II. Legal Standard

Pursuant to Rule 12(b)(6), a defendant may move to dismiss a cause of action if the plaintiff fails to state a claim upon which relief can be granted. In evaluating the sufficiency of a complaint under Rule 12(b)(6), courts must be mindful that the Federal Rules of Civil Procedure require that the complaint merely contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although detailed factual allegations are not required to survive a Rule 12(b)(6) motion to dismiss, a complaint that "offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal*, —U.S.—, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)). Rather, the complaint must allege sufficient facts to support a plausible claim to relief. *See id.*

In deciding a Rule 12(b)(6) motion, the Court must engage in a two-step analysis. *See id.* at 1950. First, the Court must accept as true all non-conclusory, factual allegations made in the complaint. *See Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164, 113 S. Ct. 1160, 122 L. Ed. 2d 517 (1993). Based upon these allegations, the Court must draw all reasonable inferences in favor of the plaintiff. *See Mohamed v. Jeppesen Dataplan, Inc.*, 579 F.3d 943, 949 (9th Cir. 2009). Second, after accepting as true all non-conclusory allegations and drawing all reasonable inferences in favor of the plaintiff, the Court must determine whether the complaint alleges a plausible claim to relief. *See Ashcroft*, 129 S. Ct. at 1950. Despite the liberal pleadings standards of Rule 8, conclusory allegations will not save a complaint from dismissal. *See id.*

III. Discussion

A. Whether Plaintiff's Claims are Barred as Impermissible Attempts to Privately Enforce the Food, Drug and Cosmetics Act

At the outset, Defendant argues that the Complaint should be dismissed in its entirety as an attempt to impermissibly enforce the Food, Drug and Cosmetics Act ("FDCA"), for which no private cause of action exists. *See Mot.* 1:18-23. For example, Defendant claims that "Plaintiff's Complaint is based entirely on his allegations that Allergan engaged in 'off-label' promotion of Botox Cosmetic; specifically, that Allergan's marketing, promotion, and packaging of Botox Cosmetic allegedly encourages physicians to use a single vial of Botox Cosmetic for treatments for more than one patient when the FDA-approved label says that a vial of Botox Cosmetic is for 'single patient use.'" *Id.* 1:20-23. It follows, according to Defendant, that

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Plaintiff's claims represent "an impermissible attempt to privately enforce the FDCA and related regulations . . . require[ing] the Court to invade the FDA's exclusive authority to enforce and restrain violations of the FDCA and related regulations." *Id.* 1:23-26. To a limited extent, the Court agrees.

The FDCA grants authority to the FDA to oversee the safety of drugs and provides that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). This statutory provision bars any private right of action to "redress alleged violations of the FDCA." *In re Epogen & Aranesp Off-Label Marketing & Sales Practices Litigation*, 590 F. Supp. 2d 1282, 1287 (C.D. Cal. 2008) ("*In re Epogen*") (quotation and citation omitted), *aff'd sub nom, United Food & Commercial Workers Cent. Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, No. CV 09-56118, 2010 WL 4128490 (9th Cir. Oct. 21, 2010). In fact, "the right to enforce the provisions of the FDCA lies exclusively within the federal governments' domain, by way of either the FDA or the Department of Justice." *Id.* This not only prohibits a plaintiff from expressly seeking to enforce the FDCA, but also from using "state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA." *Id.* at 1290-1291; *see also Loreto v. Procter & Gamble Co.*, ___ F. Supp. 2d ___, 2010 WL 3471752 (S.D. Ohio Sept. 3, 2010 ("A purported state-law claim does not exist where the 'claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist").

In *In re Epogen*, the plaintiffs alleged that certain pharmaceutical companies unlawfully promoted an FDA approved drug "for unsafe, off-label uses" in violation of the federal Racketeer Influenced and Corrupt Organization Act ("RICO"), California's Unfair Competition Law ("UCL") and California's False Advertising Law ("FAL"). *In re Epogen*, 590 F. Supp. 2d at 1287. Specifically, the plaintiffs claimed that the defendants' conduct included "foster[ing] the false belief that [the drug] was safe for off-label uses . . . [and] [m]arketing and promoting use [of the drug] outside of the approved FDA indication." *Id.* This Court concluded that even though the complaint in that case avoided explicit references to "misbranding," the case was "largely an [impermissible] attempt to bring a private cause of action for violations of the FDCA." *Id.*

Of critical importance, however, is the court's explanation that while a plaintiff "may not use other federal statutes or state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA," a plaintiff may nevertheless bring other claims such as fraud upon properly pleaded allegations of false, misleading or omitted material facts.

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See id. at 1290-91, *see also In re Epogen & Aranesp Off-Label Marketing and Sales Practices Litigation*, MDL 08-1934 PSG, 2009 WL 1703285, at *7 (C.D. Cal. June 17, 2009) ("*In re Epogen II*") (explaining that the "Court never held that Plaintiffs' claims were *preempted* by the FDCA," just that state law could not serve as an end around of the restriction on private enforcement actions). Stated somewhat differently, a plaintiff may not ground his claims on violations of the FDCA, but can assert other federal or state law claims independently actionable without reliance on the FDCA.

To a limited degree, the Court agrees with Defendant's suggestion that Plaintiff's UCL and FAL claims are based on conduct promoting Botox for off-label use. *See Mot.* 7:16-18. For example, Plaintiff alleges, *inter alia*, that Defendant "encouraged [Plaintiff and purported class members] to use one vial of Botox Cosmetic on multiple patients, *contrary to the product's label*," *Compl.* ¶ 2 (emphasis added), that Defendant "knew that a single vial of the Product was neither intended nor permitted for use on multiple patients," *id.* ¶ 4, that Defendant failed "to disclose and/or adequately disclosure material information, including the nature of the vials as single-use and not multi-use," *id.* ¶ 149, and that Defendant's conduct violated "federal laws prohibiting advertising or representations of *off-label usage* of drugs and the misbranding of drugs," *id.* ¶ 111 (emphasis added). These, and related allegations, are like the allegations in *In re Epgen*, which the Court concluded "largely constitute[d] an attempt to shoehorn allegations that [Defendant] had engaged in off-label promotion in violation of the FDCA into . . . state consumer fraud causes of action." *In re Epogen*, 590 F. Supp. 2d at 1290. Thus, to the extent that Plaintiff's FAL and UCL claims rely on violations of the FDCA to create liability, Defendant's motion is GRANTED and the FDCA-related claims are dismissed WITH PREJUDICE. Nevertheless, Plaintiff's FAL and UCL claims are actionable if they include properly pleaded allegations of false or misleading representations that resulted in Plaintiff's injuries.

B. Plaintiff's Fraud-Based UCL and False Advertising Claims

Plaintiff's first cause of action is for violation of California's False Advertising Law, Cal. Bus. & Prof. Code § 17500 ("FAL"). To state a claim for false advertising, a plaintiff must allege that (1) the statements in the advertising are untrue or misleading and (2) the defendants knew, or by the exercise of reasonable care should have known, that the statements were untrue or misleading. *People v. Lynam*, 253 Cal.App.2d 959, 965 (1967). Plaintiff's second cause of action is for violation of California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 ("UCL"). The UCL prohibits "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising," as well as any act prohibited by California's

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false advertising statute. *See Ariz. Cartridge Remanufacturers Ass'n v. Lexmark Int'l, Inc.*, 421 F.3d 981, 985 (9th Cir. 2005) (quoting Cal. Bus. & Prof. Code § 17200). An "unlawful" business act under § 17200 is any business practice that is prohibited by law, whether "civil or criminal, statutory or judicially made . . . , federal, state or local." *See Mckell v. Washington Mutual, Inc.*, 142 Cal. App. 4th 1457, 1474, 49 Cal. Rptr. 3d 227 (2006) (citations omitted). A business act is "unfair" under § 17200 "if it violates established public policy or if it is immoral, unethical, oppressive or unscrupulous and causes injury to consumers which outweighs its benefits." *See id.* at 1473. Finally, a "fraudulent" business practice under § 17200 is "one which is likely to deceive the public," and "may be based on misrepresentations to the public which are untrue, and also those which may be accurate on some level, but will nonetheless tend to mislead or deceive." *See id.* at 1471. UCL claims that sound in fraud are subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) ("Rule 9(b)"). *See Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009). To state a claim under the "fraudulent prong" of the UCL, a plaintiff must allege specific representations made by the defendant, the extent to which the plaintiff relied upon the representations, and that the representations were false, misleading or otherwise fraudulent. *See In re Actimmune Marketing Litigation*, 614 F. Supp. 2d 1037, 1052 (N.D. Cal. 2009).

Plaintiff's FAL and fraud-based UCL claims rest upon the allegations that "Defendant represented that one vial of [Botox] is suitable for multiple patients[,] that a successful practice could be built on selling [Botox] on a per unit basis to the public, [and that] Defendant also failed to disclose material facts, namely, the danger and risks in using one vial of [Botox] for multiple patients." *Compl.* ¶ 137. It is also alleged that "Defendant knew or should have known that its representation that a vial of [Botox] is suitable for multiple patients and its non-disclosures were untrue or misleading," *id.* ¶ 138, and that "Plaintiff relied on Defendant's representations and non-disclosures . . . [which] played a significant part in influencing Plaintiff's decision to invest in the development of a cosmetic practice [using Botox]," *id.* ¶ 139. As both the fraud-based UCL and FAL claims "sound in fraud," the Court treats them together to determine whether the Complaint is alleged with the degree of particularity required by Federal Rule of Civil Procedure 9(b). *See Kearns*, 567 F.3d at 1125(claims "grounded in fraud" are subject to Rule 9(b)).

Rule 9(b) requires a party alleging fraud "to state with particularity the circumstances constituting fraud." *See* Fed. R. Civ. P. 9(b). To avoid dismissal for failure to meet Rule 9(b)'s pleading requirements, a complaint must "state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentation." *See Edwards v. Marin Park, Inc.*, 356 F.3d 1058, 1066 (9th Cir. 2004) (internal quotations omitted). Put

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differently, "[a]verments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003).

While Plaintiff alleges that Defendant's conduct violated the UCL under each of the unlawful, unfair and fraudulent prongs, there is no dispute that the UCL claim sounds in fraud and is subject to the heightened pleading requirements of Rule 9(b). *See Mot.* 11:27; *Opp'n* 7:12-13. Plaintiff devotes over thirty paragraphs of his Complaint to allegations of fraudulent representations or misrepresentations. Despite this, the allegations are insufficient as they do not include the "who, what, when, where [or] how of the misconduct charged." *Vess*, 317 F.3d 1106.

Plaintiff's FAL and UCL fraud allegations fall into two broad categories: (1) unlawful statements made during a lengthy advertising campaign, and (2) statements made directly to Plaintiff and potential class members by Defendant's representatives. With respect to the advertising campaign targeted towards physicians, Plaintiff cites the *Tobacco II Cases* decided by the California Supreme Court and insists that he need not "plead with an unrealistic degree of specificity that plaintiff relied on particular advertisements or statements." *See Opp'n* 12:14-15 (citing *In re Tobacco II Cases*, 46 Cal. 4th 298, 326, 93 Cal. Rrtr. 3d 559 (2009)). While this may be true in California state court, it is not true in federal court where the Federal Rules of Civil Procedure govern pleading and require "that the circumstances of the fraud must be stated with particularity." *In re Actimmune Marketing Litigation*, No. CV 08-2376, 2009 WL 3740648, at *13 (N.D. Cal. Nov. 6, 2009) ("*Tobacco II* cannot rescue plaintiffs' claims under the UCL fraudulent prong"); *see also Kearns*, 567 F.3d at 1126 (citing Rule 9(b) and affirming dismissal because Plaintiff failed to identify "what the television advertisements or other sales material specifically stated . . . when [plaintiff] was exposed to them . . . which ones he found material . . . [and] which sales material he relied upon in making his decision to buy").

In this case, plaintiff alleges that Defendant undertook misleading advertising campaigns separately targeted to consumers and physicians. *See Compl.* ¶ 46. Presumably, Plaintiff could have relied upon either—despite the target audience—and the Court examines both to determine whether Plaintiff has adequately pleaded a UCL claim. Plaintiff does not. Although the Complaint identifies certain newspapers covering the ad campaign targeted to consumers (New York Times), the celebrities associated with the ads (Virginia Madsen), and Defendants' efforts to advertise on the internet (web banners), *see id.* ¶¶ 42-46, Plaintiff never alleges that he saw any ads and relied on them in making Botox purchases and investing in his business. Moreover, while the consumer advertising sought to convince women that "they're missing out on a good

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thing," Plaintiff does not identify how that, or any other representation made to increase Botox sales, was false or misleading.

The media campaign directed at physicians suffers from many of the same pleading errors. For example, Plaintiff alleges that "news stories, journal article, and interviews with medical professionals" were used by Defendant to misrepresent the single use nature of the Botox vial. *See Compl.* ¶ 47. In one December 2002 article, "Defendant's manager of public affairs, Christine Cassiano was quoted '(Botox Cosmetic) is sold in a 100-unit vial' and ' . . . per vial, it (the dosage) is dependent on the patient and the indication for which it is being used.'" *Id.* ¶ 63. The article's author, *not* Defendant's public affairs manager, then goes on to say that "the economics behind paying for a vial that will potentially treat five, rather than just one patient with the average 20-unit dosage, have led some to create 'botox parties.'" *Id.* Not only is the only reference to using a single vial of Botox on multiple patients not attributable to Defendant, but Plaintiff does not identify how Defendant's public affairs manager's statements were false or misleading, and how they induced his reliance. Another news article identified in the complaint states that Defendant's spokeswoman Kellie Reagan would not comment on how Defendant promotes its product, but goes on and quotes other physicians who "said that Allergen's sales representatives have consistently said vials of Botox could be used for multiple patients." *Id.* ¶ 98. Plaintiff does not identify when these statements were made, who the sales representatives were and whether he actually heard them before purchasing Botox and building his practice.

The bulk of the Complaint, however, is devoted to other claims of fraud or misrepresentation, none of which meet Rule 9(b)'s pleading standards. A number of the allegations in the Complaint mention that Defendant misrepresented the single-use nature of the vials, but do not state that Plaintiff was exposed to Defendant's representations and that he detrimentally relied on them. *See id.* ¶ 49 ("Immediately after the Product was approved in 2002, Defendant targeted physicians with training options. Starting in 2002, Defendant's wrongful promotional efforts included providing, through its sales representatives, complimentary staff vials . . . During these sessions, Defendant's representatives direct that one vial of Botox Cosmetic can be used on multiple people."); ¶ 50 ("Defendant also holds training sessions for its sales representatives where multiple Allergan representatives are injected with Botox Cosmetic from the same bottle."); ¶ 54 ("Defendant, through its representatives, promoted and attended physician administered 'Botox parties' where multi-patient use of a single vial was encouraged"); ¶ 55 ("In addition, Defendant, through its representatives, affirmatively told or informed at least one practitioner that Allergan could write a letter stating that multiple use of one Botox Cosmetic vial was acceptable"); ¶ 56 ("Allergan marketed the concept of 'Botox

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Parties' to medical professionals"); ¶ 57 ("In February 2002, the Palms Casino in Las Vegas announced that it would host 'Botox Cocktail parties' two Saturdays every month"); ¶ 83 ("CME courses sponsored by Defendant were often provided by . . . a [continuing medical education] company to which Allergan donates money for injector trainings"); ¶ 86 ("Plaintiff also attended several seminars and CMEs . . . This has occurred since 2006 to the present"). Merely alleging that Defendant held continuing education seminars, promoted "Botox Parties," or made other contact with physicians without any specifics about when, with whom, that Plaintiff was involved or that the representations were false or misleading is not sufficient to meet Rule 9(b)'s heightened pleading standards.

Similarly, Plaintiff identifies certain representatives of Defendant's and alleges that they promoted Botox to him. For example, Plaintiff states that "[e]ven before Plaintiff first purchased Botox Cosmetic in 2002, Defendant's representative, believed to be Jenny Jones, would visit Plaintiff's offices to promote the Product," *Compl.* ¶ 52, and that Jenny Jones attended a 'Botox Party' hosted by Plaintiff in 2008 to "provide supplies" and promote the party, *id.* ¶ 69. Plaintiff fails to identify the false or misleading conduct of Jenny Jones, when it occurred and how he relied on it. Plaintiff's allegation that he "saw Defendant's representatives, including but not limited to, Jenny Jones, Tina Damore, Mary Bryant and other training representatives . . . demonstrate that Botox Cosmetic could be injected from one vial and used upon multiple patients," *id.* ¶ 53, does little for his fraud and false advertising claims because there is no indication when these misrepresentations actually occurred, as required by Rule 9(b).

In addition, Plaintiff points to the "Incentive Programs" created by Defendant to market Botox, as well as the nature of the vials themselves in order to allege false advertising and fraud. Briefly stated, Plaintiff alleges that Defendants knowingly packaged Botox in 50 or 100 unit vials when treatments would never use that much, giving the impression to the treating physicians that one vial could be used multiple times. *See Compl.* ¶ 73. In doing so, Defendants created a benefits program including "Botox Express Cards," which allows a patient to get ten units of Botox free after purchasing 100 units. *See id.* ¶ 77. Moreover, in 2008, Defendant sent Plaintiff a "Botox calculator" and "business plan worksheet," which calculated profits for a physician based on administering an entire vial of Botox Cosmetic. *See id.* ¶¶ 80-81. These, too, are insufficient as the allegations fail to specify that the nature of the vials or the marketing tools and methods induced reliance on Plaintiff's part. For example, Plaintiff offers no explanation for how a representation made "in 2008" could reasonable induce him to purchase Botox "starting in 2002," *see id.* ¶ 52 or to incur "marketing, staffing, equipment, and various business startup and planning expenses" for a business facility that opened in January 2008, *see id.* ¶¶ 69, 115.

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The closest Plaintiff comes to correctly pleading a false or misleading representation comes in paragraph 68 of the Complaint, where Plaintiff alleges that "In 2008, Plaintiff attended a Botox part at the Rampart Casino with one of his staff members where Allergan-retained nurse Mary Bryant trained doctors using the multi-use technique." *Id.* ¶ 68. The statement includes the what, when, where and how of the fraud, but does not include the "who." All that Plaintiff alleges is that a nurse, hired by Defendant, showed those in attendance the "multi-use" technique. When alleging fraud against a corporation, however, "the plaintiff must allege the names of the persons who made the allegedly fraudulent representations, their authority to speak, to whom they spoke, what they said or wrote, and when it was said or written." *See Edejer v. DHI Mortgage, Co.*, No. CV 09-1302 PGH, 2009 WL 1684714, at *11 (N.D. Cal. June 12, 2009) (citations omitted). Without more, the conduct of Ms. Bryant is attributable to her, not Defendant, and Plaintiff does not include any reference to Ms. Bryant's authority to speak on behalf of the corporate Defendant.

Finally, Defendant argues, and the Court agrees, that Plaintiff has not alleged facts showing that Defendant's alleged representations were false or misleading. *See Mot.* 16:7-10. In fact, the Complaint shows that Defendant's alleged representation that a single-use vial could be used multiple times is literally true. *See Compl.* ¶ 49 (alleging that Defendant sent representatives to physicians' offices and injected the contents of one vial of Botox into multiple people). Moreover, a physician can use a product however he or she deems appropriate in his or her medical judgment. *See e.g., In re Epogen II*, 2009 WL 1703285, at *4, n.2; *see also Buckman Co. v. Plaintiffs' Legal committee*, 531 U.S. 341, 350, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001) (off-label use is not unlawful). A physician could literally use the "single-use" vials multiple times and it was not unlawful to do so.

Plaintiff's heavy reliance on the United States District Court for the District of Massachusetts' opinion *In re Celexa and Lexapro Marketing and Sales Practices Litigation* does not change this Court's analysis. ___ F. Supp. 2d ___, 2010 WL 4644429 NMG (D. Mass. Nov. 10, 2010). In that case, the court found that plaintiff adequately pleaded fraud under the UCL where the Complaint included the time, place and content of alleged misrepresentations concerning the safety and efficacy of a certain drug, along with facts indicating why the representations made by the pharmaceutical company were false. *See In re Celexa*, 2010 WL 4644429, at *8. Though that case and this case do share some similarities, it is this Court's determination that Plaintiff has insufficiently pleaded the "who, what, when, where and how" of Defendant's alleged misrepresentations that leads to divergent outcomes. Whereas the court in that case determined that Rule 9(b)'s particularity requirements had been met, that is simply not the case here. *See id.* As indicated, the allegations of misrepresentations in Plaintiff's

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Complaint suffer from lack of specificity related to when the representations took place, to whom they were made, their specific content or how Plaintiff relied on them. Citing to a case with a similar factual background cannot cure Plaintiff's failure to plead the facts in this case with specificity.

The Complaint does not allege, with the proper degree of specificity, when the representations about Botox's vial were made, to whom they were made, and how Plaintiff relied upon them in purchasing Botox and building a Botox practice. As a result, Plaintiffs' false advertising and UCL claim based on fraud cannot stand.

C. Plaintiff's UCL Claim for "Unlawful" Conduct

Plaintiff's UCL claim is also based on the unlawful prong of § 17200. As discussed, an "unlawful" business act under § 17200 is any business practice that is prohibited by law, whether "civil or criminal, statutory or judicially made . . . , federal, state or local." *See Mckell*, 142 Cal. App. 4th at 1474. Defendant's business practices are allegedly unlawful because "its conduct constitutes a violation of the False Advertising Law . . . violations of FDA Regulations prohibiting off-label marketing and violations of state and administrative regulations and requirements." *Compl.* ¶ 144. First, the Court's conclusion that Plaintiff has failed to state a claim for FAL violations is equally applicable here. In addition, Defendant is correct in arguing that the Complaint "identifies only one law that Allergan allegedly violated: the FDCA." *Mot.* 9:5-6. However, for the same reasons discussed above, the UCL is not a proper vehicle for a private litigant to use to enforce the FDCA. *See In re Epogen*, 590 F. Supp. 2d at 1290 ("what the FDCA does not create directly, [the UCL] cannot create indirectly"). Presumably, the Center for Disease Control guidelines and the Nevada Board of Health Regulations are the "state and administrative regulations and requirements" that the Complaint alleges Defendant violated. *See Compl.* ¶¶ 28, 34, 144. These, however, are not laws that can serve as the basis for an unlawful-prong UCL claim, nor are they alleged to even apply to Defendant, as opposed to physicians. *See id.* ¶ 28 (CDC warning against using single-use vials for more than one patient); ¶ 38 (Nevada State Medical Board sent a letter to physicians "instructing them that one vial of Botox Cosmetic should only be used on one patient"). Plaintiff has thus failed to state a claim under the unlawful prong of the UCL.

C. Plaintiff's UCL Claim Based on "Unfair" Conduct

Finally, Plaintiff asserts a claim under the unfair prong of the UCL. It is unclear whether a plaintiff must (1) show that the harm to the consumer of a particular practice outweighs its

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utility to defendant, or (2) show unfairness that is tethered to a specific constitutional, statutory or regulatory provision. *See Janda v. T-Mobile USA, Inc.*, 378 Fed. Appx. 705, 708 (9th Cir. 2010). Plaintiff's Complaint includes allegations related to both.

First, Plaintiff argues that the Complaint adequately alleges that the potential health risks faced by a patient subjected to multiple uses of a single-use vial outweigh the usefulness of "selling a product that is not in accordance with the FDA's approved dosage amounts or with the FDA's limitations on off-label marketing." *See Opp'n* 21:5-6. This again is an attempt to impermissibly enforce the FDCA, even though phrased to avoid specific reference to that Act. Plaintiff argues that the Complaint "violates a public policy underlying a specific constitutional, statutory, or regulatory provision," because public policy, as established by the FDCA, requires that "drugs sold in the marketplace are safe, effective and not misbranded." *Opp'n* 21:15-16 (quoting 21 U.S.C. § 301, *et seq.*). More specifically, the Complaint alleges that "Defendant violated public policy established by the FDCA by misrepresenting the fact that Plaintiff could legally use the Product for more than one patient per vial." *Id.* 21:18-19. No matter how artfully the Complaint is pleaded in attempting to enforce the FDCA, Plaintiff cannot enforce the FDCA's off-label advertising provisions simply by calling it a violation of the UCL.

Finally, to the extent that the Complaint alleges unfair conduct in that Defendant misrepresented a physician's ability to use the entire contents of a Botox vial, that is a claim sounding in fraud, which the Court has already determined is lacking the particularity Rule 9(b) requires. *See Kearns*, 567 F.3d at 1122 (UCL claims sounding in fraud must meet Rule 9(b)'s particularity requirements); *see also Janda*, 378 Fed. Appx at 708 ("plaintiffs have not plausibly alleged a harm to them because they have not shown an actionable misrepresentation" by the defendant).

IV. Conclusion

Based on the foregoing, the Court determines that the portions of Plaintiff's Complaint relying on the FDCA to assert a claim under the UCL and FAL comprise an improper attempt to privately enforce the FDCA and those claims are dismissed WITH PREJUDICE. In addition, the portions of Plaintiff's UCL and FAL claims not based on FDCA violations are insufficiently pleaded. The Court therefore GRANTS WITH LEAVE TO AMEND Defendant's motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) those portion of Plaintiff's claims unrelated to enforcement of the FDCA's off-label provisions. Plaintiff must file a Fifth Amended Complaint by February 7, 2011 or the Court will dismiss the claims with prejudice.

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IT IS SO ORDERED.